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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/925,674	08/09/2001	Suzanne Cory	11686A	3390
7590 01/25/2006 Scully, Scott, Murphy & Presser 400 Garden City Plaza Garden City, NY 11530			EXAMINER KAUSHAL, SUMESH	
			ART UNIT 1633	PAPER NUMBER

DATE MAILED: 01/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/925,674

Applicant(s)

CORY ET AL.

Examiner

Sumesh Kaushal Ph.D.

Art Unit

1633

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 October 2005.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 6-10, 21 and 22 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 6-10, 21 and 22 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's response filed on 10/31/05 has been acknowledged.

Claims 1-5 and 11-20 are canceled.

Claims 6-10 and 21-22 are pending and are examined in this office action.

Applicants are required to follow Amendment Practice under revised 37 CFR §1.121. The fax phone numbers for the organization where this application or proceeding is assigned is 571-273-8300.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The references cited herein are of record in a prior Office action.

Priority

Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119 and 120 as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application); the disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The amendment filed on 05/06/04 modified the amino acid sequences of SEQ ID NO: 7 and SEQ ID NO:9, which are not supported by priority documents US 09/155,327 and AU PN8965.

The applicant states that "*The attached substitute Sequence Listing is identical to the Sequence Listing filed with the Preliminary Amendment on August 9, 2002, with the exception that SEQ ID NO: 6 and SEQ ID NO: 8 in the attached Sequence Listing are identical to those as disclosed in the instant application when originally filed in the United States under 35 U.S.C. §371 on March 29, 1999*" (response 5/6/04 page 4).

However, the applicant fails to disclose wherein the specification there is support for newly introduced subject matter that introduces SEQ ID NO: 7 and SEQ ID NO:9 as human and mouse bcl-w proteins.

The specification discloses that: "Human Bcl-w is defined by the amino acid sequence set forth in SEQ ID NO:7 and mouse Bcl-w is defined in SEQ ID NO:9. The respective nucleotide sequences from human bcl-w and mouse bcl-w are shown in SEQ ID NO:6 and SEQ ID NO:8 respectively". see spec. page 4, lines 8-10). However the amino acid sequences encoded by the nucleotide sequences of SEQ ID NO:6 and SEQ ID NO:8 do not match the amino acid sequences of SEQ ID NO: 7 and SEQ ID NO:9 respectively in view of the amendment filed on 05/06/04. Therefore the priority date of the instant application regarding the subject matter of SEQ ID NO: 7 and 9 is 05/06/04.

Claim Rejections - 35 USC § 112

Claims 6-10, 21 and 22 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the same reasons of record as set forth in the office action mailed on 04/27/05.

The scope of instant claims encompasses isolated polypeptides of SEQ ID NO:7 and SEQ ID NO:9. The applicant had filed an amendment on 05/06/004 to correct the amino acid sequences of SEQ ID NO:7 and SEQ ID NO:9. The specification discloses that:

"Human Bcl-w is defined by the amino acid sequence set forth in SEQ ID NO:7 and mouse Bcl-w is defined in SEQ ID NO:9. The respective nucleotide sequences from human bcl-w and mouse bcl-w are shown in SEQ ID NO:6 and SEQ ID NO:8 respectively". see spec. page 4, lines 8-10)

However the amino acid sequences encoded by the nucleotide sequences of SEQ ID NO:6 and SEQ ID NO:8 do not match the amino acid sequences of SEQ ID NO: 7 and SEQ ID NO:9 respectively in view of the amendment filed on 05/06/04.

For example recently filed sequence listing (05/06/04) contains Val(85) and Ala(135) instead of Leu(85) and Val(135) in the SEQ ID NO:7. Similarly the sequence listing contains Ala(2), Met(126), Glu(146), Glu (158), Ser(169), Val(170), Arg(171), Leu(174) instead of Pro(2), Ile(126), Asp(146), Asp(158), Val(169), Ser(170), Thr(171), Val(172), Val(173) in SEQ ID NO:9.

These newly introduced substitutions and/or additions are inconsistent with applicant's disclosure that human Bcl-w is defined by the amino acid sequence set forth in SEQ ID NO:7 and mouse Bcl-w is defined in SEQ ID NO:9 wherein the respective nucleotide sequences from human bcl-w and mouse bcl-w are shown in SEQ ID NO:6 and SEQ ID NO:8 respectively (see spec. page 4, lines 8-10).

In addition the applicant fails to disclose wherein the specification there is support for newly introduced subject matter that introduces SEQ ID NO: 7 and SEQ ID NO:9 as human and mouse bcl-w proteins.

As MPEP 2163.06 notes "If new matter is added to the claims, the examiner should reject the claims under 35 U.S.C. 112, first paragraph - written description requirement. In re Rasmussen, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981)."

So the subject matter of claim 6 is apparently new matter. No pages or place in the specification was cited to support this amendment. A careful review by the examiner of the specification failed to identify any support for this new limitation. Since no basis has been found to support the new claim limitation in the specification, the claims are rejected as incorporating new matter.

Claim Rejections - 35 USC § 102

Claims 6-10, and 21-22 stand rejected under 35 U.S.C. 102(b) as being anticipated by AN: Q92843 (BCLW_HUMAN, 1997), see attached PTO sequence

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search report Apr. 2005), for the same reasons of record as set forth in the office action mailed on 04/27/05.

The cited art teaches an amino acid sequence which matches 100% to the SEQ ID NO:7 of instant application (see attached PTO sequence search report for AN: Q92843 conducted Apr. 2005). Thus given the broadest reasonable interpretation to the inherent functional properties of the claimed polypeptide, the cited art clearly anticipate the invention as claimed.

Claims 6-10, and 21-22 stand rejected under 35 U.S.C. 102(b) as being anticipated by AN: P70345 (BCLW_MOUSE, 1997), see attached PTO sequence search report Apr. 2005), for the same reasons of record as set forth in the office action mailed on 04/27/05.

The cited art teaches an amino acid sequence which matches 100% to the SEQ ID NO:9 of instant application (see attached PTO sequence search report for AN: P70345, conducted Apr. 2005). Thus given the broadest reasonable interpretation to the inherent functional properties of the claimed polypeptide, the cited art clearly anticipate the invention as claimed.

Claims 6-10, and 21-22 stand rejected under 35 U.S.C. 102(e) as being anticipated by Craig et al (US 6812339, 2004), for the same reasons of record as set forth in the office action mailed on 04/27/05.

The cited art teaches a polypeptide sequence comprising 193 amino acids (SEQ ID NO: 10928), which matches 100% to the SEQ ID NO:7 of instant application (see attached PTO sequence search report for US6812339 SEQ ID NO:10928, conducted Apr.2005). Thus given the broadest reasonable interpretation to the inherent functional properties of the claimed polypeptide, the cited art clearly anticipate the invention as claimed.

Response to arguments

The applicant arguments regarding Priority, New matter and Prior art issue on response filed on 08/10/05 has been fully considered. The applicant argues that as courtesy to the examiner the applicants provides herewith side-by side comparison of SEQ ID NO:7 and 9 with priority documents. Therefore, applicants submit that the current sequences of SEQ ID NO: 7 and SEQ m NO: 9 are fully supported by the present application filed on August 9, 2001, by the parent application, and by PCT/AU97/00199 and the priority document PN8965. Applicants are therefore entitled to the priority date of PN8965 (i.e., March 27, 1996). However regarding inconsistencies between the codons in SEQ ID NO: 6 and 8, and the amino acid sequences of SEQ ID NO: 7 and 9, the applicants submit that in light of the instant disclosure including Figures 1 and 8, and the disclosure of PCT/AU97/00199 and PN8965, those skilled in the art would recognize that the **inconsistencies are results of clerical errors** in preparing the Sequence Listing.

However, applicant's arguments are found not persuasive because the disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994). The applicant fails to establish that the amendment in sequence listing of instant application are also disclosed in the prior application i.e. 09155327, PCT/AU97/00199 and PN8965).

In the instant application (09/925,674) the applicant has filed *three* versions of SEQUENCE LISTING

1. SEQLIST	Sequence Listing	05/06/2004	6
2. SEQLIST	Sequence Listing	12/31/2001	8
3. SEQLIST	Sequence Listing	08/09/2001	8

In addition the applicant has filed *eleven* versions of SEQUENCE LISTING in the US 09/155,327 to which the instant application claim priority.

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1.	SEQLIST	Sequence Listing	08/11/2003	11
2.	SEQLIST	Sequence Listing	12/30/2002	11
3.	SEQLIST	Sequence Listing	04/09/2002	8
4.	SEQLIST	Sequence Listing	01/08/2002	8
5.	SEQLIST	Sequence Listing	08/13/2001	8
6.	SEQLIST	Sequence Listing	05/12/2000	8
7.	SEQLIST	Sequence Listing	02/15/2000	8
8.	SEQLIST	Sequence Listing	12/03/1999	7
9.	SEQLIST	Sequence Listing	09/25/1998	7

In the recent response filed on 10/31/05 the applicant provided fragmented analysis of support found in the asserted priority documents, which does not provide any clear evidence that subject matter as amended was originally presented in US 09155327, PCT/AU97/00199 and PN8965, without any inconsistencies. Therefore the burden shifts to applicant to provide a sequence alignment in a clear and concise format, which would establish the priority claims without any ambiguity. In the absence of evidence to the contrary the instant claims stand rejected under Priority, New matter and Prior art rejections.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sumesh Kaushal Ph.D. whose telephone number is 571-272-0769. The examiner can normally be reached on Mon-Fri. from 9AM-5PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Nguyen can be reached on 571-272-0731.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to **571-272-0547**. For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199. The fax phone number for the organization where this application or proceeding is assigned is **571-273-8300**


SUMESH KAUSHAL
PRIMARY EXAMINER
ART UNIT 1633